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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Sujatha Karoor

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EXAMINER

BOUCHELLE, LAURA A

ART UNIT

PAPER NUMBER

3763

DATE MAILED: 06/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/990,673	Applicant(s) KAROOR ET AL.	
	Examiner Laura A. Bouchelle	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 March 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-63 is/are pending in the application.
- 4a) Of the above claim(s) 12-58 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 and 59-61 is/are rejected.
- 7) ☒ Claim(s) 62 and 63 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

Claim Rejections - 35 USC § 103

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. Claims 1, 4, 5, 8, 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Roberts et al (US 5944684) in view of Henne et al (US 4610794). Roberts discloses a system for continuous renal function replacements comprising a body 11 and inlet and an outlet defining an interior (See Fig. 2), the interior comprising a layer of urease, a layer of zirconium oxide, a layer of zirconium phosphate, and a layer of carbon (Col. 8, lines 30-34).

2. Claim 1 differs from Roberts in calling for the fluid to contact the zirconium phosphate before contacting the urease or zirconium oxide layers. However, applicant's specification gives this limitation no criticality, as it discloses the layers in a variety of orientations. Henne teaches a dialysis membrane comprising absorbents such as active carbon, zirconium oxide, zirconium phosphate, that can be used in any combination, in the same layer or in separate layers, one under the other using appropriate amounts for best results (Col. 12, lines 43-55). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to make the layers of Roberts such that the fluid passes through the zirconium phosphate layer before the urease or zirconium oxide layer as taught by Henne to get the best results.

3. Claim 8 differs from Roberts in calling for two layers of zirconium phosphate, and claim 9 calls for two layers of zirconium oxide. Henne teaches that the layers can be in any configuration that provides the best filtration of the fluid. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the layers of Roberts to have two layers of zirconium phosphate or zirconium oxide as taught by Henne to provide the best filtration of the fluid.

4. Claims 2 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Marantz et al (US 3669880) in view of Henne et al. Marantz discloses a dialysis system comprising a body with an inlet and an outlet with an interior comprising zirconium phosphate, urease, carbon and hydrous zirconium oxide that has the nitrate ion removed (Col. 4, line 67 – Col. 5, line 10).

5. Marantz lacks the limitation of claim 1 calling for the fluid to contact the zirconium phosphate before the urease or zirconium oxide. Therefore, claims 2 and 3, depending from claim 1, differ from Marantz in calling for the fluid to contact the zirconium phosphate before the urease or zirconium oxide. Henne teaches a dialysis membrane comprising absorbents such as active carbon, zirconium oxide, zirconium phosphate, and urease, that can be used in any combination, in the same layer or in separate layers, one under the other using appropriate amounts for best results (Col. 12, lines 43-55). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to make the layers of Roberts such that the fluid

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passes through the zirconium phosphate layer before the urease or zirconium oxide layer as taught by Henne to get the best results.

6. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Roberts et al in view of Henne et al as applied to claim 1 above, and further in view of Wong (US 6627164). Claim 6 differs from the teachings of Roberts in view of Henne in calling for the zirconium phosphate to have a pH of approximately 2 to 8. Wong teaches the use of zirconium phosphate at a pH of about 5 to 6 so that it can be dried to form a free flowing powder (Col. 3, lines 34-42). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the zirconium phosphate of Roberts in view of Henne to have a pH of approximately 2-8 as taught by Wong so that the zirconium phosphate can be dried to form a free flowing powder.

7. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Roberts et al in view of Henne et al as applied to claim 1 above, and further in view of Matsui et al (US 4659744). Claim 7 differs from the teachings of Roberts in view of Henne in calling for the zirconium oxide to have a pH of 6-13. Matsui teaches the use of Zirconium oxide at a pH of greater than 6 because at pH 6 and above zirconium oxide acts as a cation exchanger (Col. 1, lines 39-45). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the zirconium oxide of Roberts in view of Henne to have a pH of 6-13 as taught by Matsui so that it will act as a cation exchanger.

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8. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Marantz in view of Henne et al. Marantz discloses a dialysis system comprising an inlet and an outlet with an interior in between, where in the inlet and the outlet comprise a header 23. See Fig. 2. The device further comprises a layer of urea, a layer of zirconium phosphate, a layer of zirconium phosphate, and a layer of carbon. See Abstract. Henne teaches a dialysis membrane comprising absorbents such as active carbon, zirconium oxide, zirconium phosphate, and urease, that can be used in any combination, in the same layer or in separate layers, one under the other using appropriate amounts for best results (Col. 12, lines 43-55). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to make the layers of Marantz such that the fluid passes through the zirconium phosphate layer before the urease or zirconium oxide layer as taught by Henne to get the best results.

9. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Roberts et al in view of Henne et al as applied to claim 1 above, and further in view of Rosa et al (US 5618441). Claim 11 differs from the teachings of Roberts in view of Henne in calling for an opening for venting. Rosa teaches a dialysis machine comprising a vent to selectively vent accumulated air from the chamber (Col. 7, lines 8-12). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the teachings of Roberts in view of Henne to include a vent as taught by Rosa to vent accumulated from the chamber.

10. Claim 59 is rejected under 35 U.S.C. 103(a) as being unpatentable over Roberts in view of Navia et al (US 5618710). Claim 59 differs from Roberts in calling for a layer of modified

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urease. Navia teaches that cross-linked enzyme crystals of urease can be used in place of urease because the cross-linked urease has a greater ability to retain activity after long periods of storage (Col. 5, lines 55-65). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to replace the urease of Roberts with cross linked enzyme crystals of urease as taught by Navia so that the urease has a greater ability to retain activity after long periods of storage.

11. Claim 60 is rejected under 35 U.S.C. 103(a) as being unpatentable over Roberts in view of Navia as applied to claim 59 above, and further in view of Henne. Claim 60 differs from the teachings of Roberts and Navia in calling for the fluid entering the device to contact the zirconium phosphate layer first. Henne teaches a dialysis membrane comprising absorbents such as active carbon, zirconium oxide, zirconium phosphate, that can be used in any combination, in the same layer or in separate layers, one under the other using appropriate amounts for best results (Col. 12, lines 43-55). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to make the layers of Roberts in view of Navia such that the fluid passes through the zirconium phosphate layer before the urease or zirconium oxide layer as taught by Henne to get the best results.

12. Claim 61 is rejected under 35 U.S.C. 103(a) as being unpatentable over Roberts in view of Navia as applied to claim 59 above, and further in view of Kantorski et al (US 4386611). Claim 61 differs from the teachings of Roberts in view of Navia in calling for the interior surface of the body to be rough. Kantorski teaches a device having a rough interior surface that prevents

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laminar flow along the interior walls of the device so that the fluid inside becomes well mixed (Col. 2, lines 30-35). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Roberts in view of Navia to have a rough interior wall as taught by Kantorski that prevents laminar flow along the interior walls of the device so that the fluid inside becomes well mixed.

Claim Objections

13. Claims 62, 63 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

14. Applicant's arguments filed 3/13/06 have been fully considered but they are not persuasive.

15. Applicant argues that the references do not teach having fluid entering the device contacting ZP layer before the other layers. Although, as applicant stated, Henne does not disclose a urease layer, it does teach that the layers it discloses can come in contact with the fluid in any order, including ZP first.

Conclusion

16. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura A. Bouchelle whose telephone number is 571-272-2125. The examiner can normally be reached on Monday-Friday 8-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 517-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Laura A Bouchelle
Examiner
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